UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Plaintiff, v. PHILIPS RS NORTH AMERICA LLC, RESPIRONICS CALIFORNIA LLC, and PHILIPS HOLDING USA INC., corporations, and ROY JAKOBS, STEVEN B. C DE BACA, THOMAS FALLON, DANIEL LEONARD, and JEFF DILULLO, individuals, Defendants.	No. CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against Philips RS North America LLC, Respironics California LLC, and Philips Holding USA Inc., corporations, and Roy Jakobs, Steven B. C de Baca, Thomas Fallon, Daniel Leonard, and Jeff DiLullo, individuals (collectively, "Defendants"), and Defendants, without admitting the allegations in the Complaint, having appeared and having consented to entry of this Decree without contest and before any testimony has been taken, and the United States of America having consented to this Decree,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED AS FOLLOWS:

1. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332, and has personal jurisdiction over all parties. Venue is proper in this district under 28 U.S.C. § 1391(b) and (c).

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. §§ 301-399i.

3. For purposes of this Decree, the following definitions shall apply:

A. "Actionable Registration" shall have the meaning set forth in the Recall Remediation Plan (as defined in subparagraph 3.V. below).

B. "Affiliated Legal Entity" means in relation to Defendant Entities (as defined in subparagraph 3.G. below), any legal entity which directly or indirectly: (i) owns or controls a Defendant Entity; (ii) is owned or controlled by a Defendant Entity; or (iii) is owned or controlled by the legal entity owning or controlling a Defendant Entity, but any such legal entity will only be considered an Affiliated Legal Entity for as long as such ownership or control exists. For the purpose of this definition, a legal entity will be deemed to be controlled if: (i) more than 50% (fifty percent) of its voting stock is owned by the controlling entity; or (ii) the controlling entity has the ability to direct the business activities or appoint the majority of the directors of such legal entity. Defendants shall provide FDA (as defined in subparagraph 3.K. below) with documentation showing whether an entity is an Affiliated Legal Entity within the meaning of this paragraph, within seven (7) days of receiving a written request for such documentation.

C. "Associated Persons" means Defendants' directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including, but not limited to, individuals, partnerships, corporations, subsidiaries, franchisees, affiliates, and "doing business as" entities).

D. "Covered Respironics Facilities" means: (i) 1001 and 1010 Murry Ridge Lane, Murrysville, PA 15668 ("Murrysville Facility"); (ii) 312 Alvin Drive, New Kensington, PA 15068; (iii) 174 Tech Center Drive, Mount Pleasant, PA 15666 ("Mount Pleasant Facility"); (iv) 6501 Living Place, Pittsburgh, PA 15206; and (v) 2271 Cosmos Court, Carlsbad, CA 92011 ("Carlsbad Facility"). Defendants represent to this Court that the Carlsbad Facility ceased

manufacturing Devices (as defined in subparagraph 3.I. below) on or before December 31, 2022 and that they withdrew the establishment registration for that facility on or before January 31, 2023. If Defendants determine to resume manufacturing (as defined in subparagraph 3.P. below) at the Carlsbad Facility or transfer manufacturing operations from the Carlsbad Facility to another facility owned or operated by Defendants or an Affiliated Legal Entity, then they shall give notice to FDA and such facility shall become subject to all the provisions of this Decree applicable to the Covered Respironics Facilities. Defendants may not transfer any Device manufacturing operations at a Covered Respironics Facility to a facility owned by an Affiliated Legal Entity unless the owner of the transferee facility agrees to become a party to this Decree with regard to the transferred Device manufacturing operations and this Decree has been amended to reflect that agreement.

E. "Days" means calendar days, unless otherwise specified.

F. "Defendants' Devices" means all Devices manufactured at the Defendants' Facilities (as defined in subparagraph 3.H. below).

G. "Defendant Entities" means (i) Philips RS North America LLC ("Philips Respironics"), (ii) Respironics California LLC, and (iii) Philips Holding USA Inc.

H. "Defendants' Facilities" means (i) the Covered Respironics Facilities; (ii) the Other SRC Facilities (as defined in subparagraph 3.S. below); (iii) any facility where Rework (as defined in subparagraph 3.Y. below) operations on Defendants' Devices to effectuate Recalls RES 88058 and RES 88071 have taken or are taking place; and (iv) any facility added to this Decree pursuant to paragraph 22. However, this Decree does not apply to Devices manufactured at any Defendants' Facility to the extent that those Devices are subject to the 2017 Consent Decree (as defined in subparagraph 3.CC. below). A facility performing Rework operations as

described in clause (iii) of this subparagraph that is not owned or operated by the Defendant Entities is a Defendants' Facility for purposes of this Decree only with respect to its Rework operations on behalf of the Defendant Entities, and such a facility and the Devices manufactured therein other than the Rework Devices (as defined in subparagraph 3.Z. below) are otherwise not within the scope of this Decree.

I. "Device" shall have the meaning given to the term in 21 U.S.C. § 321(h)(1) and shall include service/repair kits that may be used to manufacture the Rework Devices.

J. "Discontinued Devices" shall include all Devices that were formerly manufactured at any of the Covered Respironics Facilities that are no longer being manufactured for United States distribution. Defendants shall submit a list of the Discontinued Devices to FDA within ten (10) days of entry of this Decree.

K. "FDA" means the United States Food and Drug Administration.

L. "Form FDA 483" means the list of inspectional observations provided by an FDA investigator at the close of an inspection.

M. "Good-Faith Attempt Process" shall have the meaning set forth in the Recall Remediation Plan.

N. "Individual Defendants" means (i) Roy Jakobs, (ii) Steven B. C de Baca, (iii) Thomas Fallon, (iv) Daniel Leonard, and (v) Jeff DiLullo.

O. "Long-Term Remediation Watch" shall have the meaning set forth in the Recall Remediation Plan.

P. "Manufacture" or "Manufacturing" or "Manufacturing operations" includes designing, manufacturing, fabricating, packing, assembling, processing, contract

sterilizing, installing, labeling, relabeling, remanufacturing, reworking, repacking, and specification development.

Q. "Medically Necessary Devices" means those Devices that FDA has determined to be medically necessary. At the time the Decree is entered, FDA considers the Devices listed in Appendix 2 to be Medically Necessary Devices. Following entry of this Decree, FDA may add or remove Devices from this definition in accordance with the procedures described in paragraph 8.A.

R. "New Foam" means the sound abatement foam used to replace or used in lieu of the PE-PUR (as defined in subparagraph 3.T. below) sound abatement foam.

S. "Other SRC Facilities" means all facilities (other than the Covered Respironics Facilities) at which Defendants' Sleep and Respiratory Care Business (as defined in subparagraph 3.AA. below) manufactures or services Devices on the date of entry of this Decree or any time thereafter, including, but not limited to, the facilities identified in Appendix 1. Defendants may not transfer any Sleep and Respiratory Care Business Device manufacturing operations from an Other SRC Facility to a facility owned or operated by an Affiliated Legal Entity unless the owner of the transferee facility agrees to become a party to this Decree with regard to the transferred Sleep and Respiratory Care Business Device manufacturing operations and this Decree has been amended to reflect that agreement by adding the facility to Appendix 1. If all of the Sleep and Respiratory Care Business operations and Devices are discontinued at a facility that is an Other SRC Facility on the date of entry of this Decree, that facility will no longer be considered an Other SRC Facility. Defendants represent to this Court that, as of the date of entry of this Decree, the facility located at 5905 Nathan Lane North, Suite 200, Plymouth, MN does not manufacture any SRC Devices (as defined in subparagraph 3.BB. below); and the

facility located at 920 SW Emkay Drive, Suite 100, Bend, OR ceased manufacturing Devices and Defendants have withdrawn the establishment registration for that Oregon facility.

T. "PE-PUR" means polyester-based polyurethane.

U. "Recall Remediation Devices" means the Replacement Devices (as defined in subparagraph 3.X. below), the Rework Devices, and the service/repair kits used to manufacture the Rework Devices.

V. "Recall Remediation Plan" means the plan submitted by Defendants to FDA (version 5), as amended on March 28, 2024, and agreed to by FDA on March 28, 2024, including any modifications thereto made in accordance with paragraph 12 of this Decree.

W. "Recalled Devices" means Devices that are subject to the Class I recalls Defendant Philips Respironics initiated on June 14, 2021 (RES 88058 and RES 88071), including any Devices that were or are added to one of those recalls after June 14, 2021.

X. "Replacement Devices" means any Devices manufactured, held, or distributed by Defendants to permanently replace the Recalled Devices to effectuate Recalls RES 88058 and RES 88071 and the Recall Remediation Plan, including, but not limited to, versions of the Recalled Devices that do not contain PE-PUR sound abatement foam.

Y. "Rework" means the process of removing PE-PUR sound abatement foam from Recalled Devices and, where applicable, replacing that foam with New Foam.

Z. "Rework Devices" means Recalled Devices from which PE-PUR sound abatement foam has been or will be removed by Defendants or their employees or agents, and, where applicable, replaced with New Foam.

AA. "Sleep and Respiratory Care Business" includes the business that the Defendant Entities identify as their "Sleep and Respiratory Care Business" on the date of entry

of this Decree or any subsequent date, including, but not limited to, the manufacturing and servicing of the Devices listed at Appendix 3 and any Devices that were manufactured or serviced by the Sleep and Respiratory Care Business on July 18, 2022 or any subsequent date, and any successor to the Sleep and Respiratory Care Business.

BB. "SRC Device" means any Device that, on the date of entry of this Decree or any subsequent date, is manufactured or serviced by or for the Sleep and Respiratory Care Business. "SRC Device" includes all Devices listed in Appendix 3, even if the manufacturing of the Device is transferred to another facility owned or operated by a different business segment or unit of the Defendant Entities or any of their subsidiaries or affiliates after entry of this Decree.

CC. "2017 Consent Decree" means the Consent Decree for Permanent Injunction entered in United States v. Philips North America LLC d/b/a Philips Medical Systems and Philips Healthcare, *et al.*, Civ. No. 17-11955 (D. Mass.).

4. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of Device that are adulterated within the meaning of 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, and installation are not in conformity with the current good manufacturing practice ("CGMP") requirements set forth in 21 C.F.R. Part 820.

5. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of Device that are misbranded within the meaning of 21 U.S.C. § 352(t) in that Defendants failed or refused to furnish material or information respecting the Devices, as required by 21 C.F.R. Part 806.

6. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k), by causing Devices to become adulterated within the meaning of 21 U.S.C. § 351(h) and/or misbranded within the meaning of 21 U.S.C. § 352(t), while such Devices are held for sale after shipment of one or more of their components in interstate commerce.

PROVISIONS APPLICABLE TO DEVICES MANUFACTURED AT THE COVERED RESPIRONICS FACILITIES

7. Upon entry of this Decree, Defendants and each and all of their Associated Persons, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a), from directly or indirectly manufacturing, holding, and/or distributing any Device at or from Covered Respironics Facilities, unless and until:

A. Defendants have completed the repair/Rework, replacement, and refund activities set forth in the Recall Remediation Plan in accordance with the recall effectiveness targets set forth in the Recall Remediation Plan;

B. The facilities, and the methods and controls used to manufacture, hold, and distribute Devices at or from the Covered Respironics Facilities are established, operated, and administered in compliance with 21 U.S.C. § 351(h) and 21 C.F.R. Parts 803, 806, and 820;

C. Defendants select and retain at their expense an independent person or persons (the "QS Expert I") to conduct inspections of the Covered Respironics Facilities and to review Defendants' procedures and methods for manufacturing, holding, and distributing Devices, to determine whether their methods, facilities, and controls are operated and administered in conformity with the Act, its implementing regulations, and this Decree. The QS Expert I shall be qualified by education, training, and experience to conduct such inspections,

have specific expertise in evaluating compliance with the requirements in 21 C.F.R. Parts 803, 806, and 820 and 21 C.F.R. § 807.81, and be without personal or financial ties (other than a consulting agreement between the parties) to Defendants' officers or employees or their families. Defendants shall notify FDA in writing of the identity of the QS Expert I within ten (10) days of entry of this Decree;

D. The QS Expert I develops a plan to inspect the Covered Respironics Facilities and the methods and controls used to manufacture, hold, and distribute Devices at the Covered Respironics Facilities (the "Work Plan"), which shall include a timetable for completion of those inspections, and submits the Work Plan to FDA for its review and written approval. The plan shall be submitted to FDA no later than thirty (30) days after entry of this Decree. The QS Expert I shall not implement the Work Plan prior to receiving FDA's written approval, and in no circumstance shall FDA's silence be construed as a substitute for written approval;

E. At Defendants' election, the QS Expert I may develop separate Work Plans for each of the Covered Respironics Facilities and submit such Work Plans separately to FDA;

F. After receiving FDA's written approval of the Work Plan, the QS Expert I performs comprehensive inspections of the Covered Respironics Facilities and submits a report concurrently to FDA and Defendants certifying in writing (i) that the QS Expert I has inspected the Covered Respironics Facilities, and the methods and controls used to manufacture, hold, and distribute Devices at such Covered Respironics Facilities; (ii) whether Defendants have adequately corrected all observations set forth in FDA's Form FDA 483 from the most recent FDA inspection of each facility; (iii) whether, based upon those inspections, Defendants' Covered Respironics Facilities, methods, and controls are operated in conformity with the Act,

its implementing regulations, and this Decree; (iv) whether Defendants have adequate procedures in place to ensure that they submit to FDA all medical device reports ("MDRs"), establish and maintain MDR event files, and conduct an investigation and evaluate the cause of each MDR event, in accordance with 21 C.F.R. Part 803; and (v) whether Defendants have adequate procedures in place to ensure that they report to FDA actions concerning Device corrections and removals, and maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA, in accordance with 21 C.F.R. Part 806. The QS Expert I shall submit the report concurrently to FDA and to Defendants, and the report shall include an evaluation of:

(i) Defendants' compliance with 21 U.S.C. § 351(h) and 21 C.F.R. Parts 803, 806, and 820;

(ii) Whether Defendants have established a plan that will provide appropriate data that demonstrate all Devices manufactured at the Covered Respironics Facilities meet all their design specifications throughout the entire service-life of the Device as reflected in its labeling and design records;

(iii) Defendants' procedures for their Corrective and Preventative Action ("CAPA") system, including, but not limited to: analyzing quality data to identify existing and potential causes of nonconforming product and other quality problems; investigating the causes of nonconformities relating to product, processes, and the quality system; identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems; verifying or validating corrective and preventive actions to ensure such actions are effective and do not adversely affect the finished Device; implementing and recording changes in methods and procedures as needed to correct and prevent quality

problems; ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; conducting and documenting adequate failure investigations; and submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review;

(iv) Defendants' processing of all CAPAs and pre-CAPA investigations since November 2021;

(v) Defendants' procedures to control received, purchased, or manufactured products to verify conformance to product specifications;

(vi) Defendants' procedures to ensure all purchased or otherwise received products and services conform to specified requirements;

(vii) Defendants' design control system, including the design change control process and performing risk analysis;

(viii) Defendants' procedures for evaluating whether changes made to the Devices manufactured at the Covered Respironics Facilities require the submission of a new premarket notification;

(ix) Defendants' procedures for receiving, reviewing, and evaluating complaints and whether Defendants maintain accurate and complete complaint files;

(x) Defendants' procedures for compliance with 21 C.F.R. Part 803 (medical device reporting);

(xi) Defendants' procedures for compliance with 21 C.F.R. Part 806 (reports of corrections and removals); and

(xii) Other issues required by the Work Plan.

For Discontinued Devices, QS Expert I's inspection and reports shall be limited to subclauses (iii), (iv), (ix), (x), and (xi) above. On the first day of the month, in the second calendar month following FDA's approval of the Work Plan and continuing until QS Expert I's completion of the Work Plan, the QS Expert I shall submit to FDA a status report on a quarterly basis regarding QS Expert I's execution of the Work Plan;

G. Defendants report to FDA in writing the actions that they have taken to: (i) address all observations brought to Defendants' attention by the QS Expert I and all observations set forth in the Form FDA 483s for the Covered Respironics Facilities from the most recent inspection of each facility; and (ii) ensure that the methods used in, and the facilities and controls used for manufacturing, holding, and distributing Devices, reporting adverse events, and reporting corrections and removals, are operated and administered and will be continuously operated and administered in conformity with the Act, its implementing regulations, and this Decree. Defendants shall include with their report a copy of a written certification from the QS Expert I that Defendants are in compliance with the Act, its implementing regulations, and this Decree. The QS Expert I may provide FDA with a separate certification for each Covered Respironics Facility;

H. The Design Expert retained under paragraph 10 reviews the design of the Replacement Devices and the Rework Devices to determine whether any changes have been made to those Devices since the most recent clearance of each Device under 21 U.S.C. § 360(k) to determine whether any such change requires the submission of a new premarket notification or whether such changes have been otherwise authorized by FDA (*e.g.*, pursuant to an FDA-authorized Rework process for RES 88058 or RES 88071), and submits a report setting forth the Design Expert's findings concurrently to FDA and Defendants;

I. FDA, as and when it deems necessary, inspects Defendants' operations to determine whether the requirements of this paragraph have been met, including whether the Covered Respironics Facilities are operated in conformity with the Act, its implementing regulations, and this Decree;

J. Defendants pay all costs and expenses incurred under paragraph 7 for FDA inspections, investigations, supervision, reviews, examinations, and analyses, at the rates set forth in paragraph 24 of this Decree; and

K. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in subparagraphs 7.A.-H. and J. of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

8. Paragraph 7 shall not apply to the following:

A. Defendants' manufacturing, processing, packaging, holding, or distributing Devices, including any Device components, parts, or accessories, that are Medically Necessary Devices listed at Appendix 2, which may be updated by FDA in accordance with any of the following processes:

(i) FDA may on its own initiative add a new Device as a Medically Necessary Device, by providing Defendants with written notification.

(ii) Defendants may request that a new Device be added to Appendix 2 as a Medically Necessary Device by submitting a request to FDA in writing, which shall include the justification for the proposed addition. FDA will review the request and inform the Defendants in writing of its determination, and in no circumstance shall FDA's silence be construed as a substitute for written approval.

(iii) FDA may propose that a Device be removed from Appendix 2 by submitting a notice to Defendants in writing, which shall include the justification for the proposed deletion. Within fourteen (14) days of receipt of the written proposal, Defendants shall provide to FDA either: (1) written notice that Defendants agree with the removal of the Device from Appendix 2, in which case Defendants shall provide to FDA a written plan to effectuate the removal within ten (10) days after submission of Defendants' notice to FDA; or (2) written notice that Defendants disagree, including a written rationale for why Defendants believe the Device proposed for removal should remain on Appendix 2 as a Medically Necessary Device. FDA will review Defendants' notice and inform the Defendants in writing of its determination. If FDA confirms the removal of the Device from Appendix 2, Defendants shall provide to FDA a written plan to effectuate the removal within ten (10) days after receipt of FDA's written notice of the deletion. In no circumstance shall FDA's silence be construed as a substitute for written approval.

(iv) The determination of whether a Device should be added to or deleted from Appendix 2 is committed to FDA's sole discretion and is not subject to judicial review.

B. Defendants' manufacturing, processing, packaging, holding, or exporting Devices, including any Device components, parts, or accessories, that are intended solely for export from the United States, provided that:

(i) The Devices are not Recall Remediation Devices, unless (1) all registered U.S. patients who could be remediated with the specific Recall Remediation Device model to be exported and who were determined to have had an Actionable Registration at least forty-five (45) days prior to entry of this Decree have been remediated; (2) at the time of

export, for the immediate prior month, Defendants have met all the timeframes in the Recall Remediation Plan for determining whether patients have an Actionable Registration, performing the Good-Faith Attempt Process, and creating and fulfilling orders for patients with Actionable Registrations for all registered U.S. patients who could be remediated with the specific Recall Remediation Device model to be exported; and (3) Defendants have in stock a sufficient number of Devices to address the projected remediation demand in the U.S. for such Recall Remediation Device model for the next twelve months;

(ii) Defendants identify all Devices to be exported with a specific code, number, or identifier along with the serial and lot numbers that readily identify the Devices as intended solely for export;

(iii) Defendants establish controls and documentation for all Devices to be exported to assist with the monitoring and tracking of the exported Devices and to prevent their reimportation into the United States, except for the purpose of a failure investigation by Defendants to investigate a complaint;

(iv) Defendants provide FDA with an action plan Defendants intend to implement in the event that Defendants become aware of a customer or supplier that has attempted to import, or has imported, into the United States a Device that was intended for export only; and

(v) The requirements of 21 U.S.C. § 381(e) or 21 U.S.C. § 382 are met.

C. Defendants' manufacturing, processing, packaging, holding, or distributing Devices, including any Device components, parts, or accessories, that:

(i) Are provided by Defendants to testing laboratories solely for the purpose of development, testing, verification, validation, or qualification activities necessary to complete: (1) the Recall Remediation Plan or any other activity required under this Decree; (2) evaluation of the potential health risks associated with the Recalled Devices or any activity intended to support ongoing civil litigation related to the Recalled Devices; (3) designs and design changes or modifications in accordance with 21 C.F.R. Part 820 or comparable international standards or requirements; (4) changes to production, process controls, manufacturing procedures, or production or manufacturing-related equipment; (5) complaint investigations and corrective and preventive actions and investigations; (6) changes to components, raw materials, parts, suppliers, or supplier processes or services; or (7) preparation of a premarket submission to FDA or comparable foreign regulatory authority or notified body;

(ii) Are intended solely to implement a correction or removal action to reduce, mitigate, or eliminate a risk to health or remedy a potential violation, provided that Defendants: (1) notify FDA within ten (10) business days of initiating such correction or removal under 21 C.F.R. Part 806, unless exempt from such notification requirements, and (2) cease the removal or correction, and/or the manufacturing, processing, packaging, labeling, holding, and/or distribution of the Devices required for such correction or removal, including any component, part or accessory, if FDA so instructs in writing. If Defendants' implementation of any such correction or removal requires export of Recall Remediation Devices, the export amount of each model of a Recall Remediation Device shall not exceed the amount proportionate to the ex-U.S. market share for such Device model, unless Defendants have in stock a sufficient number of Recall Remediation Devices to address the projected remediation demand in the U.S. for such Recall Remediation Device model for the next twelve

months, in which case the export amount to implement the correction or removal shall not exceed the excess Recall Remediation Devices for that model in addition to the proportionate ex-U.S. market share. For purposes of this provision, "ex-U.S. market share" means the ex-U.S. percentage of total unit sales in the full year preceding June 1, 2021;

(iii) Are intended solely for the purpose of: (1) conducting any clinical investigations and testing in accordance with 21 C.F.R. Part 812; or (2) exporting Devices for use in clinical investigations performed outside of the United States provided that Defendants also satisfy all of the conditions in subparagraph 8.B.;

(iv) Are intended solely for the purpose of performing routine service or maintenance on, or are intended as a service replacement or service loaner for, Devices that are in the possession of customers and consignees of Defendants or other users, or are consumables, accessories, or replacement parts intended to support the use of Devices in the possession of customers or other users, as set forth at Appendix 4;

(v) Are intended solely for use in nonclinical research (including bench testing, market research, validation, human factors, and animal testing) or other non-human or nonclinical use, provided that Defendants label such Devices as "For [Research Use/Animal Use/Demonstration/Validation Testing] Only – Not for Human or Clinical Use" and they are used in a manner that does not involve use on human beings; or

(vi) Have been requested by Defendants in writing pursuant to this subparagraph, provided that: (1) Defendants submit to FDA the documentation and justification for such request that FDA deems necessary; and (2) the Defendants' request has been granted by FDA in writing. In no circumstance shall FDA's silence be construed as a substitute for written approval.

D. Defendants' manufacturing, processing, packaging, or holding (but not distributing) Devices in anticipation of FDA's approval, clearance, or de novo authorization for a new or modified Device, including, without limitation, design and development work for new or modified Devices. Defendants understand and agree that any Devices manufactured under this subparagraph shall be destroyed, at Defendants' sole expense, in the event FDA determines that the Devices are not approved, cleared, or authorized, unless FDA, in writing, waives destruction of such Devices to permit a resubmission by the Defendants to achieve such approval, clearance, or authorization.

E. Defendants' importing and distributing Devices that are components, parts, or accessories necessary to manufacture, repair/Rework, or process any Device that Defendants are permitted to manufacture, repair/Rework, or process under this Decree.

F. Defendants' holding at the Mount Pleasant Facility Devices that were not manufactured, processed, or packaged at any of the Covered Respironics Facilities and distributing such Devices from the Mount Pleasant Facility.

ADDITIONAL PROVISIONS APPLICABLE TO THE RECALL REMEDIATION DEVICES AND THE RECALL REMEDIATION PLAN

9. Defendants shall take the following additional steps regarding the New Foam used in certain Recall Remediation Devices:

A. Within ten (10) days of entry of this Decree, Defendants shall select and retain at their expense an independent person (or persons) who is qualified by education, training, and experience to review and evaluate the testing data and analyses described in subparagraph 9.B. and who is without personal or financial ties (other than a consulting agreement between the parties) to Defendants' officers or employees or their families (the

"Testing Expert"). Defendants shall notify FDA in writing of the identity of the Testing Expert within five (5) days of retaining such expert;

B. Within ninety (90) days of entry of this Decree, the Testing Expert shall review and evaluate Defendants' plan for assuring the safety of the New Foam they are using to manufacture the Replacement Devices and the Rework Devices to assess whether the testing that has already been performed on the New Foam, coupled with the testing that is in process and planned, will enable a determination that the New Foam does not degrade during the labeled service life of the Device and addresses all other risks posed by PE-PUR sound abatement foam without introducing new or similar health concerns;

(i) The Testing Expert's review and evaluation shall include review of the protocols for and, where available, results for the following types of testing and analyses to evaluate the biocompatibility of Replacement Devices and Rework Devices containing New Foam used in breathing gas pathways in healthcare applications:

(1) biocompatibility evaluation and risk management review from exhaustive testing under worst case conditions of Replacement Devices and Rework Devices containing New Foam that would be representative testing for the duration of the labeled service life of the Device, per ISO 18562-1, including:

(a) biocompatibility hazard identification per clause 4.3 of ISO 18562-1, which includes consideration of the New Foam materials of manufacture, intended additives, process contaminants and residues, substances released in normal use, degradation products from normal use that might pass into the patient via the gas pathways (including consideration of clinically relevant use case scenarios such as low and high environmental temperatures, low and high environmental humidity, extended hours of use, or

other clinically relevant use cases that may affect the stability of the New Foam); physical characteristics of the New Foam material; and the effects of any hygienic processing steps required before use or re-use, to the extent that a cleaning method is consistent with the Device labeling;

(b) risk assessment of Devices containing New Foam per clause 4.4 of ISO 18562-1; and

(c) biocompatibility evaluation plan of Devices containing New Foam per clause 4.5 of ISO 18562-1;

(2) analytical and toxicological risk assessments of volatile organic compounds ("VOCs") emission from Replacement Devices and Rework Devices containing New Foam per ISO 18562-1 and ISO 18562-3;

(3) particulate matter ("PM") testing of Replacement Devices and Rework Devices containing New Foam per ISO 18562-1 and ISO 18562-2; and

(4) to the extent that the considerations of subclauses (1)-(3) are not sufficiently mitigated by testing and/or justifiable scientific rationale, such that plausible scenarios exist whereby the New Foam may degrade and a patient may come into direct contact with measurable amounts of particulates from such degraded New Foam, chemical characterization and biological evaluation of the New Foam per ISO 10993;

(ii) The Testing Expert shall submit a report summarizing the Testing Expert's evaluation to Defendants and FDA concurrently, within thirty (30) days of completion of the review and evaluation described in clause (i) of subparagraph 9.B. If the Testing Expert does not believe the testing and analyses that Defendants have performed, coupled with the testing and analyses that are in process and planned, will enable a determination whether the

New Foam does not degrade during the labeled service life of the Device and addresses all other risks posed by PE-PUR sound abatement foam that led to RES 88058 and RES 88071 without introducing new or similar health concerns, the Testing Expert shall identify specific gaps and proposed testing, analyses, or other information or activities that Defendants shall perform or provide to enable such a determination. The copy of the report submitted by the Testing Expert to FDA shall be accompanied by a copy of all protocols, reports, results, and data that the Testing Expert reviewed as part of the Testing Expert's evaluation;

(iii) If the Testing Expert identifies gaps and proposes testing, analyses, or other information or activities pursuant to clause (ii) of subparagraph 9.B., within ninety (90) days of receipt of the report, Defendants shall submit to FDA a plan for addressing such gaps and the proposed testing, analyses, or other information or activities, to the Testing Expert's satisfaction, and a timetable for completion of those activities. The timetable shall be subject to FDA approval. Defendants shall ensure the implementation and completion of the testing, analyses, or other information or activities proposed by the Testing Expert in accordance with the FDA-approved timetable;

(iv) Within ninety (90) days of the completion of the testing and analyses described in clause (i) of subparagraph 9.B. (including any testing or analyses ongoing or planned at the time of the Testing Expert's initial review and evaluation), and any additional testing, analyses, or other information or activities to address the Testing Expert's findings pursuant to clause (ii) of subparagraph 9.B., the Testing Expert shall submit concurrently to FDA and to Defendants the Testing Expert's determination whether the New Foam used in the Replacement Devices and Rework Devices does not degrade during the labeled service life of the

Device and addresses all other risks posed by the PE-PUR sound abatement foam that led to RES 88058 and RES 88071 without introducing new or similar health concerns; and

(v) After reviewing the Testing Expert's report, FDA will notify Defendants whether they appear to have ensured the New Foam used in the Replacement Devices and Rework Devices does not degrade during the labeled service life of the Device and addresses all risks posed by the PE-PUR sound abatement foam that led to RES 88058 and RES 88071 without introducing new or similar health concerns.

10. Within ten (10) days of entry of this Decree, Defendants shall select and retain at their expense an independent person (or persons) who is qualified by education, training, and experience to review and evaluate the design information and data described in subparagraphs 7.H. and 10.A. and who is without personal or financial ties (other than a consulting agreement between the parties) to Defendants' officers or employees or their families (the "Design Expert"). Defendants shall notify FDA in writing of the identity of the Design Expert within five (5) days of retaining such expert. The Design Expert shall take the following additional steps regarding the Recall Remediation Devices:

A. The Design Expert shall review the design of the Recall Remediation Devices (with the exception of the safety of the New Foam, which is to be reviewed separately under paragraph 9) to determine whether those Devices have undergone appropriate and necessary testing; their designs have undergone a thorough risk analysis; and their designs have been properly verified and validated. Within sixty (60) days of entry of this Decree (or, for Recall Remediation Devices added after entry of this Decree, within sixty (60) days after such Recall Remediation Devices are authorized by FDA and added to the Recall Remediation Plan per paragraph 12 of this Decree), the Design Expert shall submit concurrently to FDA and

Defendants a report with the Design Expert's preliminary assessment of the design of the Recall Remediation Devices and a work plan for the remainder of its review, if the Design Expert determines that the review requires more than sixty (60) days to complete. Once the Design Expert's review is complete, the Design Expert shall submit concurrently to FDA and Defendants either: (i) a certification that the Recall Remediation Devices have undergone appropriate and necessary testing, the designs of the Recall Remediation Devices have undergone a thorough risk analysis, and their designs have been properly verified and validated; or (ii) a report identifying necessary corrective actions;

B. If the Design Expert identifies the need for corrective actions, within thirty (30) days of the submission of the report, Defendants shall submit a written report to FDA that details the specific corrective actions Defendants will take and a timetable to address any deficiencies identified by the Design Expert. The timetable shall be subject to FDA approval. Defendants shall ensure the implementation of the corrective actions detailed in the report;

C. As the corrective actions detailed in the report described in subparagraph 10.B. are completed, Defendants shall notify the Design Expert. The Design Expert shall promptly inspect and verify whether those actions have been completed to the Design Expert's satisfaction and in accordance with the timetable approved by FDA. If the Design Expert determines that an action has not been completed to the Design Expert's satisfaction, the Design Expert promptly will so notify Defendants. Upon FDA approval of the timetable under subparagraph 10.B., and thereafter on the first day of each month, the Design Expert shall submit concurrently to FDA and Defendants a table that succinctly summarizes the Design Expert's findings regarding whether the actions have been completed to the Design Expert's satisfaction and in accordance with the timetable approved by FDA;

D. FDA may, in its discretion and without prior notice, periodically inspect the Covered Respironics Facilities and undertake such additional examinations, reviews, and analyses to verify whether the actions reported to have been completed have in fact been completed in a satisfactory manner. If FDA determines that an action that has been reported to be completed is inadequate, FDA will notify Defendants in writing, and Defendants shall take appropriate action in accordance with a timetable that is subject to approval by FDA; and

E. When the Design Expert determines that all the corrective actions identified in the timetable approved by FDA pursuant to subparagraph 10.B. have been completed to the Design Expert's satisfaction, the Design Expert shall provide Defendants with a written certification that all of the actions have been completed. Once the certification has been issued, Defendants shall promptly submit the Design Expert's certification to FDA.

11. Defendants shall take the following steps to ensure their manufacture of the Rework Devices complies with the Act, 21 C.F.R. Part 820, and this Decree:

A. Within five (5) days of entry of this Decree, Defendants shall select and retain at their expense an independent person or persons (the "QS Expert II"), to perform an evaluation of Defendants' Facilities, methods, and controls for manufacturing, holding, and distributing the Rework Devices and to determine whether Defendants' Facilities, methods, and controls for manufacture of the Rework Devices are operated and administered in conformity with the Act, its implementing regulations, and this Decree;

B. The QS Expert II shall be qualified by education, training, and experience to conduct such inspections, have specific expertise in evaluating compliance with the CGMP requirements for Devices as set forth in 21 C.F.R. Part 820, be without personal or financial ties (other than a consulting agreement between the parties) to Defendants' officers or employees or

their families, and may, if Defendants choose, be the same person or persons described as the QS Expert I in subparagraph 7.C. Defendants shall notify FDA in writing of the identity of the QS Expert II within five (5) days of retaining such expert;

C. Within sixty (60) days of retaining a QS Expert II, the QS Expert II shall complete inspections of Defendants' manufacturing operations related to the Rework Devices at all Defendants' Facilities where Rework operations are taking place, and report to Defendants and FDA in writing whether the methods for manufacturing, holding, and distributing the Rework Devices are operated and administered in conformity with 21 C.F.R. Part 820; provided, however, that QS Expert II's inspections shall not include any Defendants' Facility that was inspected by FDA within one-hundred eighty (180) days prior to the entry of this Decree if such FDA inspection did not result in any Form FDA 483 observations. This review shall include evaluation of the supplier controls used by Defendants for any contractors or suppliers performing any manufacturing operations for the Rework Devices;

D. Within thirty (30) days of receipt of the QS Expert II's report, Defendants shall submit a written report to FDA that details the specific corrective actions Defendants will take and a timetable to address any deficiencies identified by the QS Expert II. The timetable shall be subject to FDA approval. Defendants shall ensure the implementation of the corrective actions detailed in the report in accordance with the approved timetable;

E. As the corrective actions detailed in the report described in subparagraph 11.D. are completed, Defendants shall notify the QS Expert II. The QS Expert II shall promptly inspect and verify whether those actions have been completed to the QS Expert II's satisfaction and in accordance with the timetable approved by FDA. If the QS Expert II determines that an action has not been completed to the QS Expert II's satisfaction, the

QS Expert II promptly will so notify Defendants. Upon FDA approval of the timetable under subparagraph 11.D., and thereafter on the first day of each month, the QS Expert II shall submit concurrently to FDA and Defendants a table that succinctly summarizes the QS Expert II's findings regarding whether the corrective actions have been completed to the QS Expert II's satisfaction and in accordance with the timetable approved by FDA;

F. FDA may, in its discretion and without prior notice, periodically inspect Defendants' Facilities where Rework operations are taking place and undertake such additional examinations, reviews, and analyses to verify whether the actions reported to have been completed have in fact been completed in a satisfactory manner. In the event that FDA determines that an action that has been reported to be completed is inadequate, FDA will notify Defendants in writing, and Defendants shall take appropriate action in accordance with a timetable that is subject to approval by FDA; and

G. When the QS Expert II determines that all of the corrective actions identified in the timetables approved by FDA pursuant to subparagraphs 11.D. and 11.F. have been completed to the QS Expert II's satisfaction, the QS Expert II shall provide Defendants and FDA with a written certification that all the actions have been completed and that Defendants' facilities, methods, and controls for manufacture of the Rework Devices are operated and administered in conformity with the Act, its implementing regulations, and this Decree.

12. Defendants shall complete the repair/Rework, replacement, and refund activities set forth in the Recall Remediation Plan, and implement the Recall Remediation Plan, in accordance with the recall effectiveness targets set forth in the Recall Remediation Plan.

A. In the event Defendants determine that a change to the Recall Remediation Plan is required to continue to effectively and efficiently implement the repair/Rework,

replacement, refund, or other related recall activities for RES 88058 or RES 88071, Defendants shall provide notice to FDA in their ongoing bi-weekly meetings with FDA (or any successor communication agreed to by Defendants and FDA) as documented in written minutes provided by Defendants to FDA after each bi-weekly meeting and in written notice. If FDA has comments on or objections to the proposed revisions to the Recall Remediation Plan, FDA will provide written notice to Defendants within thirty (30) days of receipt of notice of the proposed revisions, and Defendants shall address those comments and objections, and submit a revised proposed plan to FDA for review within thirty (30) days of receipt of FDA's comments. In no circumstance shall FDA's silence be construed as a substitute for written approval of the proposed changes. After receiving FDA's written approval of the revised plan, Defendants shall continuously implement the plan until they have completed the repair/Rework, replacement, and refund activities set forth in the Recall Remediation Plan in accordance with the recall effectiveness targets set forth in the Recall Remediation Plan.

B. If FDA determines, based on information that was not available or provided to FDA prior to the approval of the Recall Remediation Plan or any change approved pursuant to subparagraph 12.A., that additional actions are necessary to address the risks posed by the Recalled Devices, FDA will notify Defendants in writing of its concerns and any additional actions FDA believes are necessary. Defendants shall submit their written response to FDA's notice within thirty (30) days of receipt, including a description of any changes Defendants propose to the Recall Remediation Plan to address FDA's concerns. Within thirty (30) days of receipt of the Defendants' response, FDA will notify Defendants in writing whether it approves the revised Recall Remediation Plan and, if not, of its comments and/or objections to Defendants' proposal. In no circumstance shall FDA's silence be construed as a substitute for

written approval. Defendants shall address FDA's comments and/or objections, if any, within ten (10) days of receipt. After receiving FDA's written approval of the revised Recall Remediation Plan, Defendants shall continuously implement the revised plan until they have completed the repair/Rework, replacement, and refund activities set forth in the Recall Remediation Plan in accordance with the recall effectiveness targets set forth in the Recall Remediation Plan.

13. Defendants agree to pay to the United States Treasury a percentage of net revenue from any sale of Medically Necessary Devices distributed solely pursuant to subparagraph 8.A. between the date of entry of this Decree and the date that FDA issues the notification in subparagraph 7.K., at the following rates: 10% (ten percent) of net revenue between entry of the Decree and December 31, 2024; 12% (twelve percent) of net revenue between January 1, 2025 and December 31, 2025; and thereafter 25% (twenty-five percent) of net revenue. Defendants shall make the payments required by this paragraph annually by February 28th each year. The amounts paid under this paragraph shall be determined by a qualified financial auditor, who shall be paid by Defendants, acceptable to Defendants and FDA, and without former or current personal or financial ties to the Defendants or their immediate families. Defendants shall cooperate fully with the financial auditor and provide all records requested by the financial auditor to make the determination described in this paragraph. Defendants further agree, upon written request by the government, to make all documents reviewed and prepared by the financial auditor available to the government. The parties acknowledge and agree that any payment(s) made under this paragraph is (are) not a fine, penalty, forfeiture, or payment in lieu thereof for any purpose, and that such payment(s) is (are) an equitable remedy and not punitive.

PROVISIONS APPLICABLE TO ALL DEVICES MANUFACTURED AT THE OTHER SRC FACILITIES

14. Within thirty (30) days of entry of this Decree, Defendants shall retain at their expense an independent person or persons (the "QS Expert III") to inspect each of the Other SRC Facilities. The inspections required by this paragraph are intended to provide information to Defendants and FDA and are not based on recent adverse inspection findings at these facilities by FDA.

A. The qualifications of the QS Expert III shall be the same as those set forth in subparagraph 7.C., and, if Defendants choose, may be the same person or persons described as the QS Expert I identified in subparagraph 7.C. or the QS Expert II identified in subparagraph 11.A. Defendants shall notify FDA in writing of the identity and qualifications of the QS Expert III as soon as they retain such person or persons.

B. Defendants shall cause the QS Expert III to conduct comprehensive inspections of the Other SRC Facilities to ensure that the methods, facilities, and controls used to manufacture, hold, and distribute Defendants' SRC Devices comply with the Act, its implementing regulations, and this Decree. The inspections shall include, but not be limited to, an evaluation of Defendants' design control and CAPA procedures, supplier controls, Defendants' processing of all CAPAs in the two years prior to the date the inspection commences, and compliance with 21 C.F.R. Parts 803 and 806. The inspections of all the Other SRC Facilities shall be completed no later than two hundred seventy (270) days after the date of entry of this Decree.

C. Within thirty (30) days of the completion of each inspection of one of the Other SRC Facilities, the QS Expert III shall prepare a written report of the QS Expert III's inspection that certifies to FDA: (i) that the QS Expert III has inspected the

facility; and (ii) whether the methods, facilities, and controls used to manufacture, hold, and distribute SRC Devices at that Other SRC Facility are in compliance with the Act, its implementing regulations, and this Decree. The QS Expert III shall submit the inspection report concurrently to Defendants and FDA.

D. Within thirty (30) days of receipt of the QS Expert III's report of an inspection of one of the Other SRC Facilities, Defendants shall submit a written report to FDA that details the specific corrective actions Defendants will take and a timetable to address any deficiencies identified by the QS Expert III. The timetable shall be subject to FDA approval, and in no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall ensure the implementation of the corrective actions detailed in the report.

E. As the corrective actions detailed in the reports described in subparagraph 14.D. are completed, Defendants shall notify the QS Expert III. The QS Expert III shall inspect and verify whether those actions have been completed to the QS Expert III's satisfaction and in accordance with the timetable approved by FDA. If the QS Expert III determines that an action has not been completed to the QS Expert III's satisfaction, the QS Expert III promptly will so notify Defendants. Upon FDA approval of the timetable under subparagraph 14.D., on a quarterly basis, the QS Expert III shall submit concurrently to FDA and Defendants a table that succinctly summarizes the QS Expert III's findings regarding whether the actions have been completed to the QS Expert III's satisfaction and in accordance with the timetable approved by FDA.

F. When the QS Expert III determines that all of the corrective actions identified in the timetable approved by FDA have been completed to the QS Expert III's satisfaction, the QS Expert III shall provide Defendants with a written certification that all of the actions have been completed and that the specific Other SRC Facility, based on the

inspection and on the satisfactory completion of the actions identified under subparagraph 14.D., is in conformity with the Act, its implementing regulations, and this Decree. Once the certification has been issued, Defendants shall promptly submit the QS Expert III's certification to FDA.

G. FDA may, in its discretion and without prior notice, inspect the Other SRC Facilities and undertake such additional examinations, reviews, and analyses as FDA deems appropriate to determine whether the methods, facilities, and controls used to manufacture, hold, and distribute SRC Devices at Other SRC Facilities are in conformity with the Act, its implementing regulations, and this Decree. If FDA determines that any of the methods, facilities, and controls used to manufacture, hold, and distribute SRC Devices at the Other SRC Facilities are not in conformity with the Act, its implementing regulations, and/or this Decree, FDA will notify Defendants of the deficiencies it observed and take such other action, if any, as FDA deems appropriate, including, but not limited to, the actions specified in paragraph 18.

H. Within thirty (30) days of receiving a notification from FDA under subparagraph 14.G., Defendants shall submit to FDA a plan of actions Defendants propose to take and a timetable for correcting the deficiencies. The timetable shall be subject to FDA approval. Defendants shall promptly correct all deficiencies noted by FDA in accordance with the FDA-approved timetable and cause the QS Expert III to reinspect and either (i) certify that the deficiencies have been corrected to assure that the facility is in conformity with the Act, its implementing regulations, and this Decree, or (ii) notify Defendants that the one or more deficiencies remain uncorrected. If one or more deficiencies have not been corrected, Defendants and the QS Expert III shall notify FDA in writing, and after Defendants

have addressed those deficiencies, the QS Expert III shall determine whether he/she may make the certification. Defendants shall then submit the certification to FDA.

I. After reviewing the QS Expert III's certification, FDA will notify Defendants whether they appear to be in compliance with the requirements set forth in subparagraphs 14.A.-F. and H.

J. Defendants shall maintain complete copies of the inspection reports and all underlying data in separate files at the Other SRC Facilities and shall promptly make the reports and underlying data available to FDA upon request.

15. In the event that Defendants fail, as determined either by the QS Expert III or FDA, to satisfactorily complete one or more actions in the timetable approved by FDA pursuant to subparagraph 14.D. or H., Defendants shall pay to the United States Treasury as liquidated damages the sum of $10,000 per action, per business day, until the action is fully implemented and completed to FDA's satisfaction. The annual total amount of such liquidated damages shall not exceed ten million dollars ($10,000,000.00) in any calendar year. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and that they do not in any way limit the ability of the United States of America to seek, or the Court to impose, civil and criminal contempt remedies based on conduct that may also form the basis for the payment of liquidated damages.

GENERAL PROVISIONS

16. Defendants shall retain an independent person or persons (the "Auditor") at Defendants' expense to conduct audit inspections of the Covered Respironics Facilities and the Other SRC Facilities. For the Covered Respironics Facilities, after Defendants have complied with subparagraphs 7.A.-H. and J. and FDA has notified Defendants in writing pursuant to

subparagraph 7.K., the Auditor shall conduct audit inspections once every six (6) months for a period of two (2) years and then once every year thereafter, for a total of five (5) years. For the Other SRC Facilities, after Defendants receive the notification pursuant to subparagraph 14.I., the Auditor shall conduct audit inspections not less than once every two (2) years for a period of four (4) years from the date of entry of this Decree, for a total of not less than two (2) audit inspections.

A. The Auditor shall be qualified by education, training, and experience to conduct such inspections, have specific expertise in evaluating compliance with the requirements for Devices set forth in 21 C.F.R. Parts 803, 806, and 820, be without personal or financial ties (other than a consulting agreement entered into by the parties) to Defendants' officers or employees or their families, and may, if Defendants choose, be the same person or persons described as the QS Expert I, QS Expert II, or QS Expert III.

B. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") analyzing whether Defendants' operations are in compliance with the Act, its implementing regulations, and this Decree, and identifying in detail any deviations from the foregoing ("Audit Report Observations"). As part of every Audit Report, except the first, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA, no later than twenty (20) days after the date the audit inspections are completed.

C. If an Audit Report contains any adverse Audit Report Observations, Defendants shall, within thirty (30) days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after

receiving the Audit Report, Defendants believe that correction of any adverse Audit Report Observation will take longer than thirty (30) days, Defendants shall, within ten (10) days of receipt of the Audit Report, propose a schedule to FDA in writing for completing corrections ("Correction Schedule") and provide justification for the additional time. Defendants shall complete their corrections within thirty (30) days, unless FDA approves the Correction Schedule in writing, in which case Defendants shall complete all corrections according to the approved Correction Schedule. Within thirty (30) days of Defendants' receipt of an Audit Report, or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the adverse Audit Report Observation(s). Within five (5) days of completing that review, the Auditor shall (i) report in writing to FDA whether each of the adverse Audit Report Observations has been corrected, and (ii) if they have not all been corrected, identify which adverse Audit Report Observations remain uncorrected, and provide an assessment of the risks of the uncorrected items and recommended corrective actions.

D. If any Audit Report identifies any adverse Audit Report Observations at the Covered Respironics Facilities, FDA may, in its discretion, require that the auditing cycle be extended or begin anew for up to two (2) years for such facilities. In addition, Defendants shall maintain complete Audit Reports and all their underlying data in separate files at Defendants' Facilities and shall promptly make the Audit Reports and underlying data available to FDA upon request.

17. Upon entry of this Decree, Defendants and each and all of their Associated Persons, who have received actual notice of this Decree by personal service or otherwise, are

permanently enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, any Device that is (i) adulterated within the meaning of 21 U.S.C. § 351(h), or (ii) misbranded within the meaning of 21 U.S.C. § 352(t);

B. Violates 21 U.S.C. § 331(k), by causing any Device, including any component of any Device, to become (i) adulterated within the meaning of 21 U.S.C. § 351(h), or (ii) misbranded within the meaning of 21 U.S.C. § 352(t), while such Device is held for sale after shipment of one or more of its components in interstate commerce; and/or

C. Results in the failure to implement and continuously maintain the requirements of this Decree.

18. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analysis of samples, a report or data prepared or submitted by Defendants, the Design Expert, the QS Expert I, the QS Expert II, the QS Expert III, or the Auditor, or any other information, that Defendants have violated the Act or its implementing regulations or have failed to comply with any provision of this Decree, or that additional corrective actions are necessary to achieve compliance with the Act, its implementing regulations, or this Decree, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate actions, including, but not limited to, the following:

A. Cease manufacturing, holding, distributing, storing, and/or servicing Defendants' Devices;

B. Revise, modify, or expand any report(s) prepared pursuant to the Decree;

C. Submit additional notifications, reports, or any other materials or information to FDA;

D. At Defendants' sole expense, recall, repair, replace, or refund the purchase price of adulterated or misbranded Defendants' Devices, accessories, or components manufactured, distributed, and/or sold by Defendants, or that are under the custody and/or control of Defendants' agents, distributors, customers, or consumers;

E. Issue a safety alert, public health advisory, and/or press release; and/or

F. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or to bring Defendants into compliance with the Act, its implementing regulations, and this Decree.

19. Subparagraph 18.A. shall not apply to the manufacturing, processing, packaging, holding for sale, or introducing or delivering for introduction into interstate commerce of any Device that is intended solely for export from the United States, provided that: (A) Defendants identify all Devices to be exported with a specific code, number, or identifier along with the serial and lot numbers that readily identifies the Device as intended solely for export; (B) Defendants establish controls and documentation for all Devices to be exported to assist with the monitoring and tracking of the exported products and to prevent their reimportation into the United States, except for the purpose of a failure investigation by Defendants to investigate a complaint; (C) Defendants provide FDA with an action plan Defendants intend to implement in the event that Defendants become aware of a customer or supplier that has attempted to import, or has reimported, into the United States a Device that was intended for export only; and (D) the requirements of 21 U.S.C. §§ 381(e)(1) or 382 have been satisfied and documented with respect to any such Device.

20. The following process and procedures apply to any order issued by FDA under this Decree, except as provided in subparagraph 20.D. below:

A. Unless a different timeframe is specified by FDA in its order, within ten (10) days after receiving an order, Defendants shall notify FDA in writing either that: (i) Defendants are undertaking or have undertaken corrective action, in which event Defendants also shall describe the specific actions taken or to be taken and the proposed schedule for completing the actions; or (ii) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in detail and in writing the basis for their disagreement; in doing so, Defendants also may propose specific alternative actions and specific timeframes for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. This written notification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable). Defendants shall continue to diligently implement FDA's order while the matter is before the Court and unless and until the Court reverses, stays, or modifies FDA's order. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 34.

D. The process and procedures set forth in subparagraphs 20.A.-C. shall not apply to any order issued under paragraph 18 if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall immediately and

fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief.

21. Any cessation of operations described in paragraphs 18 and 20 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Act, its implementing regulations, and this Decree. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in paragraph 18 shall be borne by Defendants at the rates specified in paragraph 24.

22. FDA may order any facility owned or operated by one or more of the Defendant Entities (including their subsidiaries) other than the Covered Respironics Facilities, the Other SRC Facilities, and the facilities subject to the 2017 Consent Decree, that manufactures, services, and/or distributes Devices in interstate commerce to be fully subject to the provisions of this Decree as though the facility had been listed as an Other SRC Facility when the Decree was entered, if FDA: (A) inspects the facility after the date of entry of this Decree and provides written notice of the inspection findings, and (B) after reviewing Defendants' response to those findings (provided such response is received within fifteen (15) business days of receipt of the inspection findings), determines that the inspection findings would result in an inspection classification of Official Action Indicated ("OAI"). For any facility added as an Other SRC Facility after (A) and (B) are met, if a subsequent inspection finds violations of the Act or its implementing regulations, FDA may order Defendants to take any or all of the actions described in paragraph 18.

23. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' Facilities and take any other measures necessary to monitor and to ensure continuing compliance with the terms of this

Decree. During such inspections, FDA representatives shall be permitted to: access buildings, equipment, in-process and finished materials, containers, and labeling therein; take photographs and make video recordings; take samples of Defendants' materials and products, containers, and labeling; and examine and copy all records relating to the manufacture, holding, and distribution of any and all Devices. The inspections shall be permitted upon presenting a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

24. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $116.47 per hour and fraction thereof per representative for inspection work; $139.61 per hour or fraction thereof per representative for analytical or review work; $0.67 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

25. Within ten (10) days of the entry of this Decree, Defendants shall post a copy of this Decree in the employee common areas at Defendants' Facilities where employees are located and on Defendants' intranet website in such a manner to ensure that it will be viewed by

such employees. Defendants shall ensure that the Decree remains posted in its employee common areas and on their intranet website for as long as the Decree remains in effect.

26. Within twenty (20) days after the entry of this Decree, Defendants shall provide a copy of this Decree, by email (with affirmative acknowledgment of review and receipt), personal service or certified mail (restricted delivery, return receipt requested), to their Associated Persons with responsibility for the manufacture and/or distribution of Devices at Defendants' Facilities. Within twenty-five (25) days of the entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all persons or entities who have received a copy of this Decree pursuant to this paragraph, and attaching copies of the executed certified mail return receipts or email with affirmative acknowledgment of review and receipt.

27. In the event that Defendants become associated, at any time after the entry of this Decree, with new Associated Persons, Defendants shall: (A) within ten (10) days of the commencement of such association, provide a copy of this Decree to each such Associated Persons by email (with affirmative acknowledgment of review and receipt), personal service or certified mail (restricted delivery, return receipt requested); and (B) provide to FDA within thirty (30) days after the end of each calendar quarter an affidavit stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all persons or entities who received a copy of this Decree pursuant to this paragraph, and attaching copies of the executed email or certified mail return receipts.

28. The obligations under this Decree of each Individual Defendant (or any Substitute Individual Defendant, as defined below) shall apply only to the extent of the Individual Defendant's (or the Substitute Individual Defendant's) authorities, responsibilities, and/or

conduct at Defendant Entities. If, and for so long as, an Individual Defendant or an employee of a Defendant Entity ceases to be employed by or act on behalf of such Defendant Entity or any of its subsidiaries, affiliates, and/or "doing business as" entities, then, provided that a Substitute Individual Defendant is added to the Decree as described below, that Individual Defendant or employee shall no longer be subject to the terms of the Decree and shall be liable only for such Individual Defendant's act(s) or failure(s) to act under this Decree prior to the time such Individual Defendant ceased to be employed by or to act on behalf of the Defendant Entities. An Individual Defendant shall notify FDA within twenty (20) days after said Defendant ceases to be employed or otherwise act for all of the Defendant Entities (including any of subsidiaries, affiliates, and/or "doing business as" entities). Within thirty (30) days of such separation, Defendant Entities shall designate an individual with the equivalent position and responsibilities to be substituted as an Individual Defendant ("Substitute Individual Defendant") and notify FDA of the identity, starting date, and nature of employment of the Substitute Individual Defendant. After Defendant Entities notify FDA of an appropriate Substitute Individual Defendant, FDA and Defendant Entities shall submit a joint stipulation to the Court identifying the Substitute Individual Defendant and requesting that the Court effect the substitution by order. The Substitute Individual Defendant added to this Decree shall be bound by the Decree in the same manner as the Individual Defendants originally named in the Decree.

29. Defendants shall notify FDA in writing at least fifteen (15) days before any change in ownership, character, or name of their businesses, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation(s), the creation or dissolution of partnerships, subsidiaries, franchisees, affiliates, or "doing business as" entities, or any other change in the corporate structure of the Defendant Entities, or in the sale or assignment of any

business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Defendants shall provide a copy of this Decree to any potential successor or assignee at least fifteen (15) days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) days prior to such assignment or change in ownership.

30. All notifications, correspondence, and communications required to be sent to FDA by the terms of this Decree shall be sent via electronic mail to the Program Division Director, FDA, Office of Medical Device & Radiological Health, Division 1, One Montvale Avenue, Fourth Floor, Stoneham, MA 02180 at oradevices1firmresponse@fda.hhs.gov. All submissions should reference the case name and civil action number.

31. If Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by or pursuant to this Decree, then, on written notice of the United States of America in this proceeding, Defendants shall pay to the United States Treasury the sum of fifteen thousand dollars ($15,000) in liquidated damages for each day such violation continues, an additional sum of fifteen thousand dollars ($15,000) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree, and an additional sum in liquidated damages equal to twice the retail value of each shipment of Devices that are adulterated, misbranded, or otherwise in violation of the Act, its implementing regulations, and/or this Decree. The annual total amount of such liquidated damages shall not exceed twenty million dollars ($20,000,000.00) in any calendar year. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and that they do not in any way limit the ability of the United States of America to seek, or the Court to impose, civil

and criminal contempt remedies based on conduct that may also form the basis for the payment of liquidated damages.

32. Defendants may petition FDA in writing to extend any deadline or time frame provided herein, and FDA may grant such extension without seeking leave of Court. However, any such petitions shall not become effective or stay any deadlines or the imposition of any payments under this Decree unless granted by FDA in writing.

33. Should the United States of America bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States of America for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

34. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. When contested by Defendants, FDA's decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

35. This Decree resolves only those claims set forth in the Complaint. Defendants specifically state and agree that entry of this Decree does not preclude (and no provision of this Decree shall limit or impair the United States' ability to pursue) any criminal charges; criminal or civil penalties; civil or administrative monetary claims arising under the False Claims Act, 31 U.S.C. §§ 3729-3733, Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, or Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; common law claims; breach of contract

claims; debarment; and/or exclusion in connection with any conduct of Defendants, including the conduct alleged in the Complaint filed with this Decree.

36. No sooner than five (5) years after Defendants receive the notifications from FDA pursuant to subparagraphs 7.K. and 14.I., Defendants may petition this Court for relief from this Decree. If Defendants have maintained a state of continuous compliance with this Decree, the Act, and its implementing regulations during the five (5) years preceding Defendants' petition, Plaintiff will not oppose such petition.

37. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED, this _____ day of _____, 2024.

_____
UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the entry of the foregoing Decree.

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U.S. Department of Justice

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RESPIRONICS CALIFORNIA LLC
Individually and on behalf of
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RESPIRONICS CALIFORNIA LLC

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Individually and on behalf of
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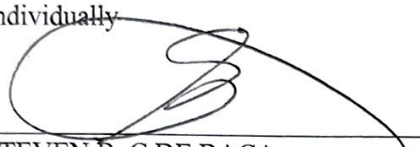

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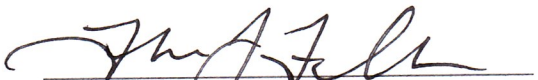

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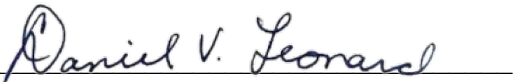

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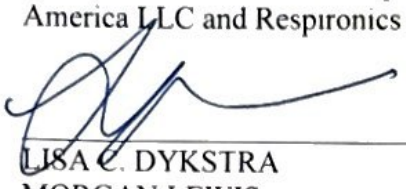

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APPENDICES

Appendix 1: Other Sleep and Respiratory Care Facilities

Block 6 & 7, No. 129, 2nd Industrial Ave., Tang Xia Yong Village, Yan Luo Sub-district, Bao An District, Shenzhen, Guangdong, 518105, CHINA

Coyol Free Zone And Business Park, Building B37, Coyol Alajuela, Costa Rica

Respironics Deutschland GmbH & Co. KG, Gewerbestr. 17 Herrsching Bavaria, DE 82211*

*This facility is an Other SRC Facility under this Decree, but it will be subject to the requirements in paragraphs 14-16 only if it directly or indirectly introduces, delivers for introduction, or causes the introduction or delivery for introduction, into interstate commerce a Device, other than a shipment to another Covered Respironics Facility for the sole purpose of (1) performing a failure investigation or (2) rework of non-conforming product that will be returned to Respironics Deutschland.

Appendix 2: Medically Necessary Devices

Device Name	K Number / Exempt Status	Product Code
EncoreAnywhere	K091319	BZD
BiPAP S/T ventilatory support system intended for use by lower weight patient populations (40-66 lbs) in accordance with the controls agreed upon by SRC and FDA	K102465	MNS
BiPAP AVAPS ventilatory support system intended for use by lower weight patient populations (40-66 lbs) in accordance with the controls agreed upon by SRC and FDA	K102465	MNS
Disposable/FEP/Invasive Circuits	K982454	MNT
Body Position Sensor - Dx	K940013	MNR
Cannula Style Thermocouples	K913396	BZG
Care Orchestrator	K181053	MNT; CAW; BZD; CBK; NOU
Care Orchestrator Essence;	K183226	MNS; MNT; BZD; CBK; NOU
Care Orchestrator Essence 4.3 USB Release;	K183226	MNS; MNT; BZD; CBK; NOU
Care Orchestrator Essence, Japan	K183226	MNS; MNT; BZD; CBK; NOU
Care Orchestrator;	K152356	BZD; CBK; MNS; MNT; NOU
DreamMapper	K152356	BZD; CBK; MNS; MNT; NOU
CPAP VALVES	K950397	BYE
Crystal Trace Piezo Sensor	K923402	BZQ
Disposable 22mm non-heated passive and heated active circuits;	Exempt	BZO
Disposable 15 mm non-heated passive and heated active circuits;	Exempt	BZO
Disposable 15mm MPV circuit	Exempt	BZO
Disposable Adult/Ped Heated Active Circuit;	K110398	BZE
Disposable Heated Wire Circuits;	K110398	BZE
Disposable Adult/Ped Heated Passive Circuit	K110398	BZE
Drain, Tee (water trap)	Exempt	BYH

PC Direct;	K090539	MNS
Omnilab Direct;	K090539	MNS
ECG electrode	K991105	DRX
ECG wireset;	K040595	OLV; OLZ
Sleepware G3;	K040595	OLV; OLZ
Sleepware;	K040595	OLV; OLZ
Encore/Encore Pro Data Management System;	K010263	BTT; BZD
EncoreAnywhere;	K092818	MNS
Flow Sensor;	K963380	BZC
FloTrak CO2 Sensor	K963380	BZC
DirectView Data Management System;	K121623	MNT
Encore Anywhere;	K121623	MNT
Universal Battery Pack (UBP2);	K121623	MNT
OMNILAB DIRECT	K121623	MNT
H2 Heated Humidifier	K030090	BTT
Heated Humidifier - MR850	K073706	BTT
Masimo MS Series	K100428	DQA
Mouthpiece, Angled;	Exempt	BYP
Mouthpiece, Straight;	Exempt	BYP
Mouthpiece, Angled Disposable;	Exempt	BYP
Mouthpiece, Reusable	Exempt	BYP
Multiple - Invasive;	Exempt	CAE
Flex Trach Adaptor 15 cm, 22M/15F-15F;	Exempt	CAE
Flex Trach Adaptor 15 cm, 22M/15F-22F	Exempt	CAE
Opti Chamber Valved Holding Chamber	K962822	CAF
OptiChamber Diamond with Lite Touch mask	K110293	NVP
Passover Humidifier	K945782	BTT
Patient Circuits	Exempt	CAI
Performance Tubing 6’	K140424	BZE
Performance Tubing;	Exempt	BYX
Low Range Cabinet Flow Meter;	Exempt	BYX
Oxygen Manifold Kit	Exempt	BYX
PLM Sensor	K940014	BZQ
Pressure Valve	K963250	BZD
Pro-Flow and Pro-Flow Plus Cannula Sensors;	K982293	MNR
Pressure Transducer Airflow Sensor (PTAF);	K982293	MNR
PTAF 2, 3, Lite	K982293	MNR
Remote Alarm	K913423	CBK
REMstar Heated Humidifier;	K090243	BZD
Encore Pro 2 Data Management System;	K090243	BZD
Universal Battery Pack (UBP2)	K122769	BZD
Respironics Disposable Heated Wire Circuits;	K110398	BZE

Disposable Adult/Ped Heated Active Circuit;	K110398	BZE
Disposable Adult/Ped Heated Passive Circuit	K110398	BZE
Roll Stand, DreamStation 2;	Exempt	FOX
Roll Stand, DreamStation;	Exempt	FOX
Roll Stand, BiPAP A-series;	Exempt	FOX
Roll Stand, OmniLab Advanced +;	Exempt	FOX
Roll Stand, Trilogy Evo;	Exempt	FOX
Wheelchair Mount, Trilogy Evo;	Exempt	FOX
Mounting Bracket, Trilogy Evo ;	Exempt	FOX
Roll Stand, SPRS-2 (H-111 cm);	Exempt	FOX
Mount, EV300	Exempt	FOX
Sleepmapper;	Exempt	OUG
Payer Integration Software;	Exempt	OUG
Omnilab Conncect;	Exempt	OUG
AOM;	Exempt	OUG
Encore Basic;	Exempt	OUG
DreamStation Cellular Modem;	Exempt	OUG
DreamStation Wi-Fi Accessory;	Exempt	OUG
HL7 Interface Utility;	Exempt	OUG
DreamStation Link Module;	Exempt	OUG
PR1 Wired/Wireless Modems	Exempt	OUG
Sleepware G3 Event Detection Software	K142988	MNR; OLV; OLZ
Snoring Microphone	K940015	MNR
Thermistor Cannula Style	K960851	BZQ
Trilogy Nurse Call Adaptor Cable	K083526	CBK
DirectView Data Management System;	K093416	CBK
Trilogy Nurse Call Adaptor Cable	K093416	CBK
Universal Battery Pack (UBP2);	K093905	CBK
Trilogy Nurse Call Adaptor Cable	K093905	CBK
Trilogy Nurse Call Adaptor Cable;	K181170	CBK
Dual Limb Active Exhalation Valve;	K181170	CBK
Nurse Call Adaptor Cable – Alarm Open/Closed;	K181170	CBK
Nurse Call Rj9 Adapter Cable Open;	K181170	CBK
12/24V Battery Cable w/terminals or adapter;	K181170	CBK
External Flow Sensor Assembly Adult/Pediatric;	K181170	CBK
External Flow Sensor Assembly Pediatric/Infant	K181170	CBK
Trilogy Nurse Call Adaptor Cable;	K181166	CBK; NOU
Dual Limb Active Exhalation Valve;	K181166	CBK; NOU
Nurse Call Adaptor Cable – Alarm Open/Closed;	K181166	CBK; NOU
Nurse Call Rj9 Adapter Cable Open;	K181166	CBK; NOU
12/24V Battery Cable w/terminals or adapter;	K181166	CBK; NOU

External Flow Sensor Assembly Adult/Pediatric;	K181166	CBK; NOU
External Flow Sensor Assembly Pediatric/Infant;	K181166	CBK; NOU
Universal Battery Pack (UBP2);	K113053	MNS
DirectView Data Management System;	K113053	MNS
ProChamber Valved Holding Chamber	K032809	CAF
CoughAssist	K002598	NHJ
CoughAssist;	K122111	BYI; NHJ
Simply Clear	K122111	BYI; NHJ
Cough Assist T70	K121955	NHJ
Esprit/V200 Ventilator with APRV Option	K110083	CBK
Everflo/Everflo Q/L4;	K061261	CAW
OPI and non-OPI;	K061261	CAW
EverFlo Quiet;	K061261	CAW
Transfill;	K061261	CAW
Ultrafill Quiet;	K061261	CAW
EverFlo;	K061261	CAW
Everflo Ultrafill	K061261	CAW
A40 Heated Humidifier;	K121623	MNT
SimplyGo POC;	K111885	CAW
SimplyFlo POC;	K111885	CAW
SimplyGo Mini POC	K111885	CAW
Trilogy 100 BT International;	K083526	CBK
Trilogy 100 Ventilator;	K083526	CBK
Garbin Ventilator BT;	K083526	CBK
Trilogy 100 Ventilator BT, U.S.;	K083526	CBK
Trilogy EC Ventilator;	K083526	CBK
Trilogy 200 Ventilator;	K093416	CBK
Trilogy 200 Ventilator BT;	K093416	CBK
Trilogy 200 Ventilator BT International;	K093416	CBK
Garbin Plus Ventilator;	K093416	CBK
Trilogy 202 Ventilator;	K093905	CBK
Trilogy Evo Universal Ventilator;	K181170	CBK
Trilogy Evo Ventilator;	K181166	CBK; NOU
Trilogy EV300	K181166	CBK; NOU
A30 Heated Humidifier;	K113053	MNS
V200 Ventilator	K102054	CBK
V200 Ventilator with Intelli-Trak Option	K110795	CBK
V60 Ventilator	K082660	MNT
V60 with PPV and Auto-Trak +	K102985	MNT
Assess Low Range Peak Flow Meter	K902292	BZH
Asthma Check;	K962925	BZH

Peak Flow Meter	K962926	BZH
Chest Shell and components	K895849	BYT
Heated Humidifier - HC100	K915460	BTT
Heated Humidifier - HC500	K953392	BTT
Heated Humidifier - MR410	K913367	BTT
Millenium M10;	K043006	CAW
OPI & non-OPI;	K043006	CAW
Millennium Transfill	K043006	CAW
NEV-100	K910947	BYT
Oasis Humidifier	K964653	BTT
Quantum Respiratory Effort Sensor	K913395	BZG
SmartSleep, Deep Sleep Headband	Exempt	HCC
Stardust 2; Stardust I, II	K052573	MNR

Appendix 3: SRC Devices

Device Name	K Number / Exempt Status	Product Code
AF531 SE FFM	K101129	CBK
AF541 SE FFM	K101130	CBK
AF541 EE Full Face Mask	K150639	BZD
AF541 FFM	K101130	MNS
AF531 FFM	K101131	MNS
AmaraView FFM	K082866	BZD
EncoreAnywhere	K091319	BZD
BiPAP S/T ventilatory support system;	K102465	MNS
BiPAP AVAPS ventilatory support system	K102465	MNS
Disposable/FEP/Invasive Circuits	K982454	MNT
Body Position Sensor - Dx	K940013	MNR
Bronchoscopy Elbow	K132168	BZD
Bronchoscopy Elbow; Bronchoscopy Elbow, Click Style	K103395	BZD
Cannula Style Thermocouples	K913396	BZG
Care Orchestrator	K181053	MNT; CAW; BZD; CBK; NOU
Care Orchestrator Essence;	K183226	MNS; MNT; BZD; CBK; NOU
Care Orchestrator Essence 4.3 USB Release;	K183226	MNS; MNT; BZD; CBK; NOU
Care Orchestrator Essence, Japan	K183226	MNS; MNT; BZD; CBK; NOU
Care Orchestrator;	K152356	BZD; CBK; MNS; MNT; NOU
DreamMapper	K152356	BZD; CBK; MNS; MNT; NOU
Amara View SE FFM	K023135	CBK

CPAP VALVES	K950397	BYE
Crystal Trace Piezo Sensor	K923402	BZQ
Disposable 22mm non-heated passive and heated active circuits;	Exempt	BZO
Disposable 15 mm non-heated passive and heated active circuits;	Exempt	BZO
Disposable 15mm MPV circuit	Exempt	BZO
Disposable Adult/Ped Heated Active Circuit;	K110398	BZE
Disposable Heated Wire Circuits;	K110398	BZE
Disposable Adult/Ped Heated Passive Circuit	K110398	BZE
Drain, Tee (water trap)	Exempt	BYH
PC Direct;	K090539	MNS
Omnilab Direct;	K090539	MNS
DreamWear Full Mask;	K140980	BZD
DreamWear Nasal Mask;	K140980	BZD
DreamWear Gel Pillows Mask;	K140980	BZD
DreamWisp Nasal Mask	K140980	BZD
Dreamwear Silicone Pillows Mask	K210844	BZD
ECG electrode	K991105	DRX
ECG wireset;	K040595	OLV; OLZ
Sleepware G3;	K040595	OLV; OLZ
Sleepware;	K040595	OLV; OLZ
Encore/Encore Pro Data Management System;	K010263	BTT; BZD
EncoreAnywhere;	K092818	MNS
Flow Sensor;	K963380	BZC
FloTrak CO2 Sensor	K963380	BZC
DirectView Data Management System;	K121623	MNT
Encore Anywhere;	K121623	MNT
Universal Battery Pack (UBP2);	K121623	MNT
OMNILAB DIRECT	K121623	MNT
H2 Heated Humidifier	K030090	BTT
Headgear; Chin Strap	Exempt	BTK
Heated Humidifier - MR850	K073706	BTT
Masimo MS Series	K100428	DQA
Mouthpiece, Angled;	Exempt	BYP
Mouthpiece, Straight;	Exempt	BYP
Mouthpiece, Angled Disposable;	Exempt	BYP
Mouthpiece, Reusable	Exempt	BYP

Multiple - Invasive;	Exempt	CAE
Flex Trach Adaptor 15 cm, 22M/15F-15F;	Exempt	CAE
Flex Trach Adaptor 15 cm, 22M/15F-22F	Exempt	CAE
Opti Chamber Valved Holding Chamber	K962822	CAF
OptiChamber Diamond with Lite Touch mask	K110293	NVP
Passover Humidifier	K945782	BTT
Patient Circuits	Exempt	CAI
Performance Tubing 6’	K140424	BZE
Performance Tubing;	Exempt	BYX
Low Range Cabinet Flow Meter;	Exempt	BYX
Oxygen Manifold Kit	Exempt	BYX
Performax FitLife SE Total Face Mask	K092648	CBK
PerforMax Pediatric EE Total FFM - Leak 1	K120562	BZD
PerforMax Pediatric EE Total FFM - Leak 2	K120562	BZD
Performax Pediatric SE Total FFM	K120639	CBK
Performax Youth Mask;	K092043	MNS
Performax, FitLife EE Total Face Mask	K091271	BZD
PLM Sensor	K940014	BZQ
PN841 SE Nasal Mask;	K151120	BZD
PN841 Nasal Mask;	K151120	BZD
Wisp Pediatric Nasal Mask SE Elbow Accessory;	K151120	BZD
Wisp Pediatric Nasal Mask	K151120	BZD
Pressure Valve	K963250	BZD
Pro-Flow and Pro-Flow Plus Cannula Sensors;	K982293	MNR
Pressure Transducer Airflow Sensor (PTAF);	K982293	MNR
PTAF 2, 3, Lite	K982293	MNR
Remote Alarm	K913423	CBK
REMstar Heated Humidifier;	K090243	BZD
Encore Pro 2 Data Management System;	K090243	BZD
Universal Battery Pack (UBP2)	K122769	BZD
Respironics Disposable Heated Wire Circuits;	K110398	BZE
Disposable Adult/Ped Heated Active Circuit;	K110398	BZE
Disposable Adult/Ped Heated Passive Circuit	K110398	BZE
Roll Stand, DreamStation 2;	Exempt	FOX
Roll Stand, DreamStation;	Exempt	FOX
Roll Stand, BiPAP A-series;	Exempt	FOX
Roll Stand, OmniLab Advanced +;	Exempt	FOX
Roll Stand, Trilogy Evo;	Exempt	FOX

Wheelchair Mount, Trilogy Evo;	Exempt	FOX
Mounting Bracket, Trilogy Evo ;	Exempt	FOX
Roll Stand, SPRS-2 (H-111 cm);	Exempt	FOX
Mount, EV300	Exempt	FOX
Sleepmapper;	Exempt	OUG
Payer Integration Software;	Exempt	OUG
Omnilab Conncect;	Exempt	OUG
Encore Basic;	Exempt	OUG
DreamStation Cellular Modem;	Exempt	OUG
DreamStation Wi-Fi Accessory;	Exempt	OUG
HL7 Interface Utility;	Exempt	OUG
DreamStation Link Module;	Exempt	OUG
PR1 Wired/Wireless Modems	Exempt	OUG
Sleepware G3 Event Detection Software	K142988	MNR; OLV; OLZ
Snoring Microphone	K940015	MNR
Therapy Mask 3100 NC/SP	K210386	BZD
Thermistor Cannula Style	K960851	BZQ
Trilogy Nurse Call Adaptor Cable	K083526	CBK
DirectView Data Management System;	K093416	CBK
Trilogy Nurse Call Adaptor Cable	K093416	CBK
Universal Battery Pack (UBP2);	K093905	CBK
Trilogy Nurse Call Adaptor Cable	K093905	CBK
Trilogy Nurse Call Adaptor Cable;	K181170	CBK
Dual Limb Active Exhalation Valve;	K181170	CBK
Nurse Call Adaptor Cable – Alarm Open/Closed;	K181170	CBK
Nurse Call Rj9 Adapter Cable Open;	K181170	CBK
12/24V Battery Cable w/terminals or adapter;	K181170	CBK
External Flow Sensor Assembly Adult/Pediatric;	K181170	CBK
External Flow Sensor Assembly Pediatric/Infant	K181170	CBK
Trilogy Nurse Call Adaptor Cable;	K181166	CBK; NOU
Dual Limb Active Exhalation Valve;	K181166	CBK; NOU
Nurse Call Adaptor Cable – Alarm Open/Closed;	K181166	CBK; NOU
Nurse Call Rj9 Adapter Cable Open;	K181166	CBK; NOU
12/24V Battery Cable w/terminals or adapter;	K181166	CBK; NOU
External Flow Sensor Assembly Adult/Pediatric;	K181166	CBK; NOU
External Flow Sensor Assembly Pediatric/Infant;	K181166	CBK; NOU
Pico Nasal Mask / Pico SE Nasal Mask	K110405 & K121631	BZD

Universal Battery Pack (UBP2);	K113053	MNS
DirectView Data Management System;	K113053	MNS
Whisper Swivel II; Disposable Swivel Passive Exhalation Port	K962203	BZD
WhisperFlow Procedure Packs	K982283	BYE
Wisp Nasal Mask;	K121631	BZD
Wisp SE Nasal Mask	K121631	BZD
Wisp Youth Nasal Mask	K140268	BZD
Amara FFM / Amara Gel FFM	K082866	BZD
Comfort Gel Blue Nasal Mask	K092835	BZD
PTrak FFM	K002465	BZD
Nuance Pro Nasal Pillow Mask	K122847	BZD
Alice Nightone	K083874	MNR
Alice PDX	K090484	MNR
Bipap Focus	K053168	MNS
BiPAP Harmony 2 & S/T	K031656	MNS
BiPAP Plus M & Heated Humidifier; Omnilab Direct	K061034	BZD
BiPAP Pro 2 & Heated Humidifier; Or Components	K043607	BZD
BiPAP Q-Series w/HT;	K113068	BZD
REMstar/BiPAP Q-Series w/HT;	K113068	BZD
REMstar Q-series CPAP w/HT	K113068	BZD
BiPAP Q-Series;	K091319	BZD
REMstar Q-Series CPAP;	K091319	BZD
BiPAP Vision;	K982454	MNT
CoughAssist	K002598	NHJ
CoughAssist;	K122111	BYI; NHJ
Simply Clear	K122111	BYI; NHJ
Cough Assist T70	K121955	NHJ
Dreamstation 2 System;	K200480	BZE; BZD
Dreamstation 2 Advanced System	K200480	BZE; BZD
DreamStation BiPAP AVAPS w/ & w/o Humidifier;	K090539	MNS
BiPAP autoSV ADV w/Hum 30cm;	K090539	MNS
System One BiPAP w/ & w/o Humidifier	K090539	MNS
DreamStation BiPAP S/T w/ & w/o Humidifier;	K090539	MNS
DreamStation BiPAP autoSV w/ & w/o Humidifier;	K090539	MNS
Omnilab Advanced/Advanced +;	K090539	MNS

BiPAP autoSV Advanced;	K090539	MNS
System One CPAP w/ & w/o Humidifier	K090539	MNS
DreamStation CPAP w/ & w/o Humidifier;	K131982	BZD
DreamStation BiPAP Auto w/ & w/o Humidifier;	K131982	BZD
Dreamstation CPAP Pro w/ & w/o Humidifier;	K131982	BZD
Dreamstation CPAP Auto w/ & w/o Humidifier;	K131982	BZD
REMstar Auto A-flex HT (Q-series);	K131982	BZD
DreamStation BiPAP Pro w/ & w/o Humidifier;	K131982	BZD
DreamStation Go CPAP;	K131982	BZD
DreamStation Go Auto CPAP;	K131982	BZD
Dreamstation GO w/ & w/o Humidifier;	K131982	BZD
DreamStation CPAP Assist	K131982	BZD
Alice PSG or components;	K040595	OLV; OLZ
Alice 6 Headbox LDE;	K040595	OLV; OLZ
Alice 6 PSG Base Station LDE;	K040595	OLV; OLZ
REMstar Plus CPAP;	K010263	BTT; BZD
REMstar Heated Humidifier	K010263	BTT; BZD
BiPAP AVAPS or S/T C-Series;	K092818	MNS
BiPAP autoSV Advanced	K092818	MNS
Esprit/V200 Ventilator with APRV Option	K110083	CBK
Everflo/Everflo Q/L4;	K061261	CAW
OPI and non-OPI;	K061261	CAW
EverFlo Quiet;	K061261	CAW
Transfill;	K061261	CAW
Ultrafill Quiet;	K061261	CAW
EverFlo;	K061261	CAW
Everflo Ultrafill	K061261	CAW
A40 Heated Humidifier;	K121623	MNT
I-Neb AAD Nebulizer w/Insight SW or Components	K052941	CAF
I-neb TIM/General Purpose	K102454	CAF
Innospire Essence; Innospire Elegance	K042655	BTI; CAF
REMstar Auto w/C-Flex & Heated Humidifier	K041010	BZD
REMstar Pro M-Series & Heated Humidifier	K072996	BZD
REMstar Pro w C Flex CPAP System	K021861	BZD
REMStar SE CPAP	K130077	BZD
REMstar SE CPAP;	K122769	BZD
Dorma CPAP;	K122769	BZD
SimplyGo POC;	K111885	CAW

SimplyFlo POC;	K111885	CAW
SimplyGo Mini POC	K111885	CAW
Trilogy 100 BT International;	K083526	CBK
Trilogy 100 Ventilator;	K083526	CBK
Garbin Ventilator BT;	K083526	CBK
Trilogy 100 Ventilator BT, U.S.;	K083526	CBK
Trilogy EC Ventilator;	K083526	CBK
Trilogy 200 Ventilator;	K093416	CBK
Trilogy 200 Ventilator BT;	K093416	CBK
Trilogy 200 Ventilator BT International;	K093416	CBK
Garbin Plus Ventilator;	K093416	CBK
Trilogy 202 Ventilator;	K093905	CBK
Trilogy Evo Universal Ventilator;	K181170	CBK
Trilogy Evo Ventilator;	K181166	CBK; NOU
Trilogy EV300	K181166	CBK; NOU
A30 Heated Humidifier;	K113053	MNS
V200 Ventilator	K102054	CBK
V200 Ventilator with Intelli-Trak Option	K110795	CBK
V60 Ventilator	K082660	MNT
V60 with PPV and Auto-Trak +	K102985	MNT
C serie CPAP / AVAPS and BiPAP S/T	K102465	MNS
LDx;	K040595	OLV; OLZ
LDxN;	K040595	OLV; OLZ
LDxS	K040595	OLV; OLZ
Digital Manometer	K904935	CAP
Innospire Mini	K060404	CAF
LifecarePressure Alarm Cat.No34-010	K894361	CAP
Lifeline Personal Response System; Communicator, autoalert help button, mobile help button, personal help button, handset	K914103	ILQ
LiquiCell CPAP Cushions	Exempt	FMP
LiteTouch Mask	K100285	CAF
Masimo Oximetry Kit	K111610	CBK; DQA; NOU
Medication Dispenser		NXQ
Meter, Peak Flow, Spirometry	K912866	BZH
Personal Best EU Peak Flow Meter;	K912866	BZH
Personal Best Full Range Peak Flow Meter	K912866	BZH
Nonin Oximetry Kit	K111378	MNS

Oasis Humidifier	K964653	BTT
Personal Best Low Range Peak Flow Meter	K933889	BZH
PLV-102 & 102b	K842876	CBK
PLVC Continuum II	K034032	CBK; NOU
Sidestream Disposable Neb and Masks	K924123	CAF
Sidestream Plus Adult Mask;	K062689	CAF
Sidestream Plus Nebulizer;	K062689	CAF
Sidestream Plus Pediatric Mask	K062689	CAF
Sidestream Reusable Neb and Masks	K991725	CAF
Sidestream Tucker The Turtle Mask;	K940888	BYG
Spectrum; Actiwatch Score	K983533	GWQ
System 22 Paediatric Mask	K940888	BYG
SleepEasy	K091112	BZD
Somnolyzer 24 x 7	K083620	MNR
Stardust 2; Stardust I, II	K052573	MNR
System 22 Aerosol Mask	Exempt	BYG
Threshold IMT	K870514	BWF
Threshold Pep	K961077	BWF
REMstar M Auto w/A-Flex CPAP	K090243	BZD
CoughAssist	K002598	NHJ
CoughAssist;	K122111	BYI; NHJ
Simply Clear	K122111	BYI; NHJ
Cough Assist T70	K121955	NHJ
Esprit/V200 Ventilator with APRV Option	K110083	CBK
Everflo/Everflo Q/L4;	K061261	CAW
OPI and non-OPI;	K061261	CAW
EverFlo Quiet;	K061261	CAW
Transfill;	K061261	CAW
Ultrafill Quiet;	K061261	CAW
EverFlo;	K061261	CAW
Everflo Ultrafill	K061261	CAW
A40 Heated Humidifier;	K121623	MNT
SimplyGo POC;	K111885	CAW
SimplyFlo POC;	K111885	CAW
SimplyGo Mini POC	K111885	CAW
Trilogy 100 BT International;	K083526	CBK
Trilogy 100 Ventilator;	K083526	CBK

Garbin Ventilator BT;	K083526	CBK
Trilogy 100 Ventilator BT, U.S.;	K083526	CBK
Trilogy EC Ventilator;	K083526	CBK
Trilogy 200 Ventilator;	K093416	CBK
Trilogy 200 Ventilator BT;	K093416	CBK
Trilogy 200 Ventilator BT International;	K093416	CBK
Garbin Plus Ventilator;	K093416	CBK
Trilogy 202 Ventilator;	K093905	CBK
Trilogy Evo Universal Ventilator;	K181170	CBK
Trilogy Evo Ventilator;	K181166	CBK; NOU
Trilogy EV300	K181166	CBK; NOU
A30 Heated Humidifier;	K113053	MNS
V200 Ventilator	K102054	CBK
V200 Ventilator with Intelli-Trak Option	K110795	CBK
V60 Ventilator	K082660	MNT
V60 with PPV and Auto-Trak +	K102985	MNT
AF421 SE FFM	K101131	CBK
AF421 FFM	K101132	MNS
AF811 FFM	K073600	BZD
ComfortFull FFM	K082866	BZD
Assess Low Range Peak Flow Meter	K902292	BZH
Asthma Mentor	K962924	BZH
Asthma Check;	K962925	BZH
Peak Flow Meter	K962926	BZH
Chest Shell and components	K895849	BYT
Contour Deluxe/Comfort/Ptrak Nasal Mask;	K991648	BZD
AP111 EE/SE Nasal Mask	K991648	BZD
EasyLife Nasal Mask	K091843	BZD
GoLife Nasal Mask;	K121623	MNT
Heated Humidifier - HC100	K915460	BTT
Heated Humidifier - HC500	K953392	BTT
Heated Humidifier - MR410	K913367	BTT
LiteTouch Mask	K100285	CAF
Mask Cushion Adhesive (AF531)	Exempt	KGX
Millenium M10;	K043006	CAW
OPI & non-OPI;	K043006	CAW
Millennium Transfill	K043006	CAW
NEV-100	K910947	BYT
Nuance Nasal Pillow Mask	K122847	BZD

Oasis Humidifier	K964653	BTT
Quantum Respiratory Effort Sensor	K913395	BZG
SM Child Nasal Mask	K883825	BYE
SmartSleep, Deep Sleep Headband	Exempt	HCC
Stardust 2; Stardust I, II	K052573	MNR
System 22 Aerosol Mask	Exempt	BYG
Total Face Mask	K992969	BZD
TrueBlue Nasal Mask;	K110405	BZD
Shimmer Full Face Mask	K142554	BZD
ComfortGel Blue FFM	K073600	BZD
ComfortGel Blue SE FFM;	K023135	CBK
ComfortClassic	K082558	BZD
Profile Lite	K082558	BZD
Comfort Lite	K082558	BZD

Appendix 4: Consumables, Accessories, and Replacement Parts

Consumables & Accessories:

1. Face Masks and Cannulas along with required Elbows, Headgears, Straps, sizing gauges and Cushions
2. Active / Passive + Heated / Non-Heated Circuits and Tubes (22mm, 15mm, 12mm) and required connectors, mounts and adaptors
3. Mouth Piece Ventilation circuit kit
4. Humidifiers, Humidification controls and chambers, water trap
5. Exhalation valves, ports, swivels and porting blocks
6. Oximetry kits including cables and power supplies
7. Bacteria filters, Foam/Air filters, Exhalation and Inspiratory filters and associated adapters and connectors
8. Trach Adapter
9. O2 inlet adapter and other inlet airpath assemblies and hose
10. NIVO controller and kits
11. Volume Control Ventilation kits
12. Aerosol Delivery kits
13. Sidestream reusable and disposable nebulizer kits
14. Pressure Valve and O2 valves
15. Roll Stands, mounting kits, circuit support arms and hangers
16. Spacers and Holding chambers
17. Peak Flow meters
18. Foot Pedals
19. O2 Manifold/Transport kit and Cylinder holder/cart
20. Test lungs
21. Modems, Networking and data cards and readers
22. Sensors and monitoring kits for monitoring patients on therapy devices

23. Sensors, cables and software for continued use of Philips Respironics Diagnostic install base of devices (capnography sensor, ProTech sensor, Software, microphones, video camera, Axis video server, cables, mounts, headbox)
24. Leads, pads and Yoke for continued use of Philips Respironics Diagnostic install base of devices
25. Diaphragm kits
26. Nurse call alarm with associated cable and adapters
27. Remote alarm along with required cables, stand and power supplies
28. Communication Cables
29. Ventilation Displays
30. Mask fitting software
31. Data Management Software and accessories
32. Patient management and engagement Software
33. Field Installable Software maintenance and upgrades
34. Carrying cases and attachment straps
35. Training materials and instructions
36. Power Supplies including Batteries, AC Power modules, DC Power modules and associated cables and chargers

Replacement parts:

All service parts as needed for service / repair of the install base of products including the following examples:

37. PCBAs (printed circuit board assemblies)
38. Modem kits
39. Humidifier repair kits
40. Blower repair kits
41. Airpath repair kits